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March 3, 2010

RECEIVED

MAR - 4 2010

AT 8:30 _____ M
WILLIAM T. WALSH
CLERK

VIA FEDERAL EXPRESS

Clerk
United States District Court
Clarkson S. Fisher Federal Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *U.S. et al., ex rel. [under seal] v. [under seal]*
Case No. 08 CV 5362 (JAP)

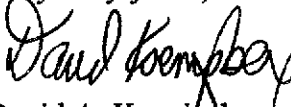
[FILED IN CAMERA AND UNDER SEAL]

Dear Madam or Sir:

We enclose for **filing in camera and under seal** in the above-captioned case Plaintiff-Relator's First Amended Complaint with attached certificate of service.

Please return a file-stamped copy of the first page of the pleading in the envelope provided for that purpose. Thank you.

Very truly yours,


David A. Koenigsberg

Encs.

cc: ✓ Hon. Joel A. Pisano, U.S.D.J. (with enclosures)
David E. Dauenhimer, Assistant U.S. Attorney (w/o enclosures)
James T. Ratner, Esq.

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Attorneys for [Under Seal]

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

-----X
UNITED STATES OF AMERICA, *ex rel.* :
[UNDER SEAL], :

Plaintiffs, :

**FIRST AMENDED
COMPLAINT**

-v- :

Civil Action No. 08-5362 (JAP)

[UNDER SEAL], :

Defendants. :
-----X

FILED IN CAMERA AND UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2)

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

-----X
UNITED STATES OF AMERICA, and :
THE STATES OF CALIFORNIA, :
DELAWARE, FLORIDA, GEORGIA, : Civil Action No. 08-5362 (JAP)
HAWAII, ILLINOIS, INDIANA, :
LOUISIANA, MASSACHUSETTS, : **FIRST AMENDED**
MICHIGAN, MONTANA, NEVADA, : **COMPLAINT FOR VIOLATION**
NEW HAMPSHIRE, NEW JERSEY, : **OF FEDERAL AND STATE**
NEW MEXICO, NEW YORK, : **FALSE CLAIMS ACTS**
OKLAHOMA, RHODE ISLAND, :
TENNESSEE, TEXAS, VIRGINIA, : **FILED UNDER SEAL**
WISCONSIN and THE DISTRICT OF : **Pursuant to 31 U.S.C. § 3730(b)(2)**
COLUMBIA, *ex rel.* HOLLY LAMPKIN, :
:
Plaintiffs, :
:
-v- :
:
JOHNSON & JOHNSON, INC., :
VISTAKON, INC., ALCON, INC., :
ALCON LABORATORIES, INC. and :
ALLERGAN, INC., :
:
Defendants. :
-----X

Plaintiff-Relator Holly Lampkin, through her attorneys Menz Bonner & Komar LLP and James T. Ratner, Esq., for her first amended complaint against defendants Johnson & Johnson, Inc., Vistakon, Inc., Alcon, Inc., Alcon Laboratories, Inc. and Allergan, Inc., alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

JURISDICTION, VENUE AND THE PARTIES

1. Relator Holly Lampkin ("Relator") is a resident of the State of Oklahoma. From 2001 to the fall of 2008, Relator was employed by defendant Johnson & Johnson, Inc. as a pharmaceutical sales representative. From this position, Relator

personally witnessed the defendants engage in illegal off-label marketing of certain ocular antibiotics: the class of drugs known as fluoroquinolones ("FQ"). Relator observed defendants give kickbacks to healthcare providers in order to induce pharmaceutical sales. Relator brings this action on behalf of herself as well as on behalf of the United States for violations of the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and against defendant Allergan, Inc, on behalf of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District Of Columbia under their respective false claims and *qui tam* laws.¹

2. Defendant Johnson & Johnson, Inc. ("J&J") is a Delaware corporation headquartered in New Jersey that is in the business of developing and marketing health care products, including pharmaceuticals. J&J has a wholly-owned subsidiary, Vistakon, Inc., located in Jacksonville, Florida. J&J, in conjunction with

¹ The applicable state false claims and *qui tam* statutes are the following: California False Claims Act, Cal. Govt. Code § 12650 *et seq.*; Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 *et seq.*; District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 1-1188.13 *et seq.*; Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*; Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-416; Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*; Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.5-1 *et seq.*; Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. § 46:437.1 *et seq.*; Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 § 5 *et seq.*; Michigan Medicaid False Claims Act, Mich. Comp. Laws. § 400.601 *et seq.*; Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61 *et seq.*; New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-2F-1 *et seq.*; New York False Claims Act, N.Y. State Finance Law §§ 187-194; Oklahoma Medicaid False Claims Act, Okla. Stat. Tit. 63 § 5053; Rhode Island False Claims Act, R.I. General Laws § 9-1.1; Tennessee False Claims Act and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* & § 71-5-181 *et seq.*; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20-931.

Vistakon, sells the drugs Iquix and Quixin throughout the United States, including New Jersey.

3. Defendant Alcon, Inc. is a pharmaceutical corporation headquartered in Switzerland. Defendant Alcon Laboratories, Inc. is a Delaware corporation with headquarters in Ft. Worth, Texas. (Alcon, Inc. and Alcon Laboratories, Inc. are hereinafter collectively referred to as "Alcon.") Alcon sells the drug Vigamox throughout the United States, including New Jersey.

4. Defendant Allergan, Inc. ("Allergan") is a Delaware corporation headquartered in Irvine, California. Allergan sells the drug Zymar throughout the United States, including New Jersey.

5. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367 and 31 U.S.C. §§ 3729, 3730(b) and 3732 in that the claims for relief in this action arise under the laws of the United States and are brought in the name of the United States. The Court has supplemental jurisdiction over the claims asserted under state law pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

6. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a) which provides that service of process may be made "at any place within or outside the United States" and because one or more of the defendants can be found in, resides and/or transacts business in this judicial district.

7. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because one or more of the defendants can be found in, resides and/or transacts business in this District. At all times relevant to this Complaint, one or more defendants regularly

conducted substantial business within this district and maintained employees and offices in this district. In addition, statutory violations, as alleged herein, occurred in this district.

8. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the “allegations or transactions” described in this Complaint. In addition, Relator is the original source of the allegations made in this complaint in that she has direct and independent knowledge of the matters set forth herein.

9. Prior to filing the instant qui tam complaint, relator voluntarily provided the information described in her complaint to the United States via a disclosure statement.

Defendants Have Each Violated And Continue To Violate The FDA Labeling Laws By Intentionally Marketing Drugs For Uses Not Approved By The FDA.

10. Defendants compete with each other for the large ocular off-label FQ market. Iquix, sold by J&J/Vistakon, is approved by the United States Food and Drug Administration (“FDA”) for the treatment of corneal ulcers only.² Vigamox and Zymar, sold respectively by Alcon and Allergan, are FDA-approved for the treatment of conjunctivitis only. Nevertheless, defendants promote on a nationwide basis the use of their respective drugs in connection with eye surgery as prophylactic antibiotics and/or for treatment of macular degeneration, each an unapproved use for all of these drugs.

11. The defendants pursue the off-label marketing of these drugs because the national market for the FDA-approved uses described above represent only 1% of the actual sales of the aforementioned drugs.

² Quixin, a lower strength version of Iquix, is FDA-approved for the treatment of conjunctivitis. The allegations made herein with respect to Iquix apply as well to the marketing of Quixin.

12. In the case of Iquix, J&J and Vistakon management personnel have admitted to Relator that only 1% of Iquix sales have been for the treatment of corneal ulcers. In order to make Iquix and Quixin profitable drugs, J&J and Vistakon have promoted to physicians use of the drugs for purposes not approved by the FDA.

13. Defendants knowingly and willfully promoted the nationwide sale and use of their respective FQ drugs, Iquix, Vigamox and Zymar, as alleged above, for certain uses not approved by the FDA. The promotion of their respective FQ drugs for these unapproved uses violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 331(a), 21 U.S.C. § 352(f). In addition, certain of these unapproved uses were not medically accepted indications for which the United States and State Medicaid programs approved reimbursement. As a result of defendants' conduct, defendants knowingly caused false/and or fraudulent claims to be submitted to the United States and the State Medicaid programs and caused other U.S. Government sponsored health insurance and health care programs and providers to purchase defendants' respective FQ drugs for unapproved uses. The vast majority of the applications of Iquix, Vigamox and Zymar for off-label use as a prophylactic antibiotic were not medically necessary. The off-label uses were a direct result of the defendants' illegal marketing efforts.

Defendants Alcon And Allergan Have Violated And Continue To Violate The Anti-Kickback Act By Providing Unlawful Inducements And Rewards To Doctors Who Prescribe Or Purchase Defendants' Drugs Knowing That These Drugs Are Being Paid For By The Medicare, Medicaid, TRICARE And Other Federal Health Insurance Programs.

14. Alcon and Allergan have violated the Federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b)(1) and (2). Defendants Alcon and Allergan have paid kickbacks to doctors nationwide in the form of, *inter alia*, free surgical kits that have a greater than

nominal value. These free and valuable surgical kits were routinely offered and delivered to physicians to induce the physicians to refer or arrange for a health care item or service to be provided and reimbursed by a federal health care insurance program, all in violation of 42 U.S.C. § 1320a-7b(b)(1) & (2). Alcon, which also manufactures ophthalmic surgical equipment, sells this equipment to doctors at a discounted rate, bundled with the free surgical kits, as an inducement to get doctors to write scripts for Xigamox, and some other drugs it markets. Allergan offered this bundling inducement until they sold their surgical division.

15. Relator has been informed by doctors that since the launch of Zymar, Allergan has paid doctors to speak off-label for Zymar by conference call, for which they received \$50.00 per call. These speakers warned their peers that if they failed to use a so-called 4th generation FQ (Zymar), they were likely to get sued for malpractice. Keynote speakers were sometimes flown in to do dinner programs on the same subject matter. Relator has also been told by doctors that they have received educational grants, up to \$50,000, if they cooperated with Allergan's schemes. Some doctors have even told relator that there was no reason for them to use J&J's antibiotic because Allergan was helping the doctors buy their practices.

16. Alcon and Allergan each ship surgical kits to individual doctors (as many as 100 such kits at a time) nationwide on a monthly basis. Such gifts grossly exceed the limits for nominal gifts set by the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services ("CMS").

17. Alcon and Allergan know that for the largest percentage of their drugs that have been paid for by Medicare, Medicaid and other federal health insurance

and health care programs, the use of those drugs was induced by the payment of illegal kickbacks by Alcon and Allergan to the health care providers who prescribed and/or used those medications. Submitting or causing the submission of claims for payment tainted by kickbacks violates the False Claims Act and parallel state laws.

18. Compliance with the Anti-Kickback Act is a condition of payment under federal health care insurance programs. Health care providers and suppliers such as Alcon and Allergan must certify their understanding "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute. . .), and on the provider's compliance with all applicable conditions of participation in Medicare." (CMS Provider/Supplier Enrollment Application Form 855). Upon information and belief, Alcon and Allergan have each made such certifications. Alcon and Allergan each knew that a health care provider and supplier must expressly agree to "abide by the [Medicare] laws, regulations and program instructions" *Id.* Because Alcon and Allergan each paid kickbacks to health care providers, they have each violated and caused providers to violate Medicare's and Medicaid's express conditions of payment. Defendants Alcon and Allergan are each liable under the False Claims Act for all money spent by federal health insurance programs and health care providers for the defendants' products tainted by kickbacks.

19. Each of Alcon's and Allergan's use of kickbacks to health care providers nationwide pre-dates the launch of Vigamox and Zymar in 2003. Prior to that time, each of Alcon and Allergan sold Ciloxan (ciprofloxacin 0.3%) and Ocuflox (ofloxacin 0.3%), respectively, by using the same illegal marketing methods as described

above until the patents for those drugs expired. Alcon and Allergan each market Vigamox and Zymar as so-called fourth generation antibiotics and each warns doctors that the failure to use these fourth generation drugs defensively will put the doctors at risk of engaging in medical malpractice. In fact, the term "fourth generation antibiotic" is a misnomer and a deceptive marketing tactic.

20. Each defendant tracks the use of their respective drugs on an individual physician basis in order to monitor the effectiveness of their illegal marketing programs. As part of her job, Relator reviewed spreadsheets containing individual physician usage information and data. These spreadsheets evidence the false claims that have been submitted as a direct result of the defendants' illegal marketing tactics.

FIRST CAUSE OF ACTION
(31 U.S.C. §§ 3729(a) (1), (2) and (3))
(All Defendants)

21. Relator incorporates by reference paragraphs 1 through 20 of this Complaint, as if set forth fully herein.

22. Defendants, by means of false and misleading off-label marketing campaigns (a) knowingly presented, or caused to be presented, to an officer or employee of the United States Government, false and fraudulent claims for payment and approval; (b) knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the Government; and (c) conspired with others to defraud the Government by getting false and fraudulent claims allowed or paid, in that Defendants made or caused false claims to be made to Medicare, Medicaid, TRICARE and other Government funded health insurance and/or health care programs, all in violation of 31 U.S.C. §§ 3729(a)(1), (2) and (3).

23. As a result of this false and fraudulent conduct the United States Government was damaged in an amount to be determined at trial.

SECOND CAUSE OF ACTION
(31 U.S.C. §§ 3729(a) (1), (2) and (3))
(Defendants Alcon and Allergan)

24. Relator incorporates by reference paragraphs 1 through 23 of this Complaint, as if set forth fully herein.

25. Each of defendants Alcon and Allergan, through a pattern of unlawful kickbacks and inducements (a) knowingly presented, or caused to be presented, to an officer or employee of the United States Government, false and fraudulent claims for payment and approval; (b) knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the Government; and (c) conspired to defraud the Government by getting false and fraudulent claims allowed or paid, in that Defendants knowingly and willfully offered and paid illegal remuneration to physicians to prescribe their products in violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b)(2), and thereby caused the submission of false claims to Medicare, Medicaid and other federal health insurance and/or health care programs, all in violation of 31 U.S.C. §§ 3729(a)(1), (2) and (3).

26. As a result of this false and fraudulent conduct the United States Government was damaged in an amount to be determined at trial.

THIRD CAUSE OF ACTION
(State False Claims Acts)
(Defendant Allergan)

27. Relator incorporates by reference paragraphs 1 through 26 of this Complaint, as if set forth fully herein.

28. Defendant Allergan, through a pattern of unlawful kickbacks and inducements (a) knowingly presented, or caused to be presented, false and fraudulent Medicaid claims for payment to officers of each of the Plaintiff States; (b) knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the Plaintiff States; and (c) conspired to defraud the Plaintiff States by getting false and fraudulent claims allowed or paid, in that Defendant Allergan knowingly and willfully offered and paid illegal remuneration to physicians to prescribe their products in violation of the respective Federal Anti-Kickback Act and analogous state laws, and thereby caused the submission of false claims to State Medicaid programs all in violation of the each Plaintiff State's false claims laws.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of herself individually, and acting on behalf, and in the name, of the Government of the United States and the Plaintiff States, respectively, demands and prays that judgment be entered against the Defendants as follows:

- a. That the Defendants shall be ordered to cease and desist from violating the False Claims Act, 31 U.S.C. §§ 3729-3732 and the respective state false claims law.
- b. On the First and Second Causes of Action under the False Claims Act, judgment shall be entered against Defendants in the amount of three times the amount of damages the United States has sustained because of Defendants' actions, plus a

civil penalty of \$11,000.00 for each act in violation of the False Claims Act, as provided by 31 U.S.C. § 3729(a), with interest.

c. On the Third Cause of Action under the respective Plaintiff States' False Claims Acts, judgment shall be entered against Defendant Allergan in the amount of three times the amount of damages each Plaintiff State has sustained because of Defendant's actions, plus a corresponding statutory civil penalty with interest.

d. That Relator shall be awarded the maximum amount available under 31 U.S.C. § 3730(d) of the False Claims Act and under each respective State False Claims Act, for bringing this action, namely, 25 percent of the proceeds of the action or settlement of the claim if the United States and/or any of the States intervenes in the matter (or pursues its claim through any alternate remedy available to the United States , 31 U.S.C. § 3730(c)(5) and/or the States), or, alternatively, 30 percent of the proceeds of the action or settlement of the claim, if the United States or any State declines to intervene.

e. That Relator shall be awarded all reasonable expenses that were necessarily incurred in prosecution of this action, plus all reasonable attorneys' fees and costs, as provided by the False Claims Act, 31 U.S.C. § 3730(d) and any applicable state law.

f. And, such other relief shall be granted in the favor of the United States, the respective States, and the Relator as this Court deems just and proper.

DEMAND FOR JURY TRIAL

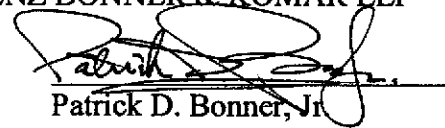
Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands trial by jury.

Dated: February 25, 2010

Respectfully submitted,

MENZ BONNER & KOMAR LLP

By:



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Attorneys for Relator Holly Lampkin

CERTIFICATE OF SERVICE

I, Lindsay Schluge, hereby certify that on March 2, 2010, I served a copy of Relator's First Amended Complaint upon the following at the addresses listed below by First Class United States Certified Mail, Return Receipt Requested:

Honorable Eric Holder, Esq.
United States Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

David E. Dauenheimer, Esq.
Assistant United States Attorney
District of New Jersey
c/o Civil Process Clerk
970 Broadway, Suite 700
Newark, New Jersey 07102-2534

And served a copy of Relator's First Amended Complaint and a computer disk with Relator's disclosures upon the following at the addresses listed below by First Class United States Certified Mail, Return Receipt Requested:

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And upon the following at the addresses listed below by First Class United States Registered Mail, Return Receipt Requested:

Hon. Bill McCollum
Attorney General of the State of Florida
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The Capitol PL-01
Tallahassee, FL 32399-1050

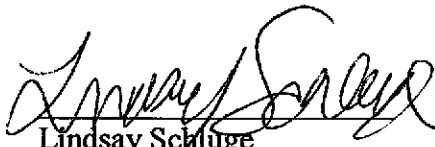
Ms. Alex Sink
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Hon. Paula T. Dow
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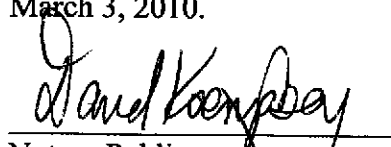
And by personal delivery upon

Hon. Andrew Cuomo
c/o Managing Clerk
Attorney General of the State of New York
120 Broadway, 24th Fl.
New York, NY 10271

Dated: New York, New York
March 3, 2010


Lindsay Schluge

Sworn to before me on
March 3, 2010.


Notary Public

David A. Koenigsberg
Notary Public, State of New York
No. 02K04792997
Qualified in Westchester County
Commission Expires Sept. 30, 2013